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FINDINGS OF FACT AND CONCLUSIONS OF LAW

SARIS, District Judge.

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INTRODUCTION AND SUMMARY

This massive nationwide multi-district class action involves the pricing of pharmaceutical drugs reimbursed by Medicare, private insurers, and patients making coinsurance payments based on average wholesale price ("AWP")[1] between 1991 and 2003. For the most part, the drugs at issue are administered by doctors for the treatment of cancer and other serious ailments.

Class plaintiffs have alleged that four pharmaceutical companies, AstraZeneca, Schering–Plough, Bristol–Myers Squibb (BMS) and Johnson and Johnson (J & J),[2] have engaged in unfair and deceptive trade practices in violation of Mass. Gen. Laws ch. 93A by grossly inflating the AWPs of certain specified drugs, which are published in commercial publications (Red Book, Medispan, First DataBank), and that these inflated prices have caused damages to Medicare, third-party payors, and patients making percentage co-payments.

The physician-administered drugs at issue in this litigation are typically quite expensive. For example, during the class period, Zoladex, manufactured by AstraZeneca to treat prostate cancer, had an AWP ranging from $320 to $450 for a one month dose; a typical dose of Taxol, manufactured by BMS to treat breast and ovarian cancer, had an AWP of over $1800; Remicade, a J & J product used to treat Crohn's Disease and rheumatoid arthritis, cost over $1000 per dose; and Intron A, manufactured by Schering–Plough and used to treat melanoma, leukemia, and hepatitis, cost nearly $500 per week for a typical recommended dosage.[3] (Rosenthal Dir. ¶ 14.) Certain drugs that are self-administered with durable medical equipment are compensated under Medicare Part B and are therefore also included in

1. See Appendix A for a glossary of terms used in this order.

2. GlaxoSmithKline settled all claims prior to trial. AstraZeneca settled the claims involving Medicare beneficiaries prior to the jury trial scheduled for June 4, 2007. However, the claims involving these classes were not settled.

3. These costs vary by disease, dosage, time period, frequency of treatment, weight of the patient and other factors. (*See* Rosenthal Dir. ¶ 14.)

the class action. The primary drug in this category is albuterol sulfate, a self-administered drug commonly administered by a nebulizer for asthma, and manufactured by Warrick, a subsidiary of Schering–Plough.

Plaintiffs' core claim is that the published AWPs for defendants' drugs are fictitious because they do not reflect the true average sales price ("ASP") to providers, like doctors and pharmacists. Because AWP is the predominant benchmark for reimbursement by the government and third-party payors, plaintiffs contend that manufacturers grossly inflate each drug's AWP to create a "spread" between the doctor's real acquisition cost and the fictitious published AWP, and that drug manufacturers then "market the spread" in order to obtain market share over a competitor's drug. Indeed, some doctors began to refer to "AWP" as "ain't what's paid." Some of the representative "markups" [4] at issue in this litigation are reflected in the chart below.

Percentage Markup

Defendant	*Drug Name*	*Spread (Year)*	*Spread (Year)*
AstraZeneca	Zoladex	40.7% (1995)	149.7% (2001)
Bristol–Myers Squibb	Blenoxane	72.8% (1998)	85.9% (2002)
Bristol–Myers Squibb	Taxol	27.0% (1997)	128.7% (2002)
Bristol–Myers Squibb	Cytoxan	257.7% (1997)	676.8% (1999)
Bristol–Myers Squibb	Rubex	180.7% (1995)	66.2% (2001)
Bristol–Myers Squibb	Vepesid	70.7% (1995)	1131.7% (1999)
Johnson & Johnson	Remicade	32.1% (1999)	31.9% (2001)
Schering–Plough	Proventil	53.4% (1993)	28.6% (2001)
Warrick (Schering)	albuterol sulfate	186.8% (1995)	651.4% (2002)

(PX 4030 at ¶ 38, Table 1.) [5]

This bench trial involved two Massachusetts classes. One class, Class 2,[6] consists of third-party payors ("TPPs") in Massachusetts that reimburse Medicare beneficiaries for their statutory twenty percent coinsurance obligations under Medicare, known as Medigap insurance or supplemental insurance. The other class of plaintiffs, Class 3,[7] consists of all third party payors, end-payors, consumers who make coinsurance payments, and consumers who have no insurance for these drugs in Massachusetts and who pay for drugs based on AWP.[8]

The bench trial spanned twenty days, included nearly forty witnesses, and involved hundreds of documents and deposition transcripts. In essence, the evidence established that the Medicare system cre-

4. Except where otherwise noted, I use the term "spread" and "markup" interchangeably.

5. See PX 4030 at ¶ 38 n. 55 for the specific National Drug Codes ("NDCs") for each drug in the chart.

6. See Appendix B for Class 2 definition.

7. See Appendix C for Class 3 definition.

8. The class does not include persons who make flat co-pays for every drug no matter what the price (like $10) because they are not affected by an inflated AWP. Also, very few people pay for the drugs at issue entirely out of pocket because they are so expensive. (Rosenthal Dir. ¶ 24.) About 10 percent of the population with employer-sponsored coverage pays coinsurance for a physician's office visit, and the typical coinsurance rate is 20 to 25 percent.

ated perverse incentives by pegging the nationwide reimbursement for billions of drug transactions a year to a price reported by the pharmaceutical industry without any oversight. Many pharmaceutical companies unscrupulously took advantage of that flawed AWP system by establishing secret mega-spreads between the fictitious reimbursement price they reported and the actual acquisition costs of doctors and pharmacies. These spreads grossly exceeded the standard industry markup. The publication of false, inflated AWPs caused real injuries to the government, insurers, and patients who were paying grossly inflated coinsurance payments for critically important, often life-sustaining, drugs. Once the mega-spreads became widely known, the conduct was still egregious under the unfairness prong of Chapter 93A because neither the third party payors nor the government could move quickly or effectively to fix the problem. In 2003, Congress finally fixed the problem by moving to a reimbursement system not based on AWP.

I make the following findings with respect to the individual defendants:

1. *AstraZeneca* acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for Zoladex which grossly exceeded actual physician acquisition costs by as much as 169% and then marketing these mega-spreads between the physician's acquisition costs and the AWP reimbursement benchmark in order to induce doctors to buy its drug based on the drug's profitability. The spread on Zoladex exceeded 100% from 1998 forward. The Court finds damages of $4,451,429 to Class 3. The Court needs additional information to calculate damages for Class 2.

2. *Bristol–Myers Squibb* acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for five drugs, which grossly exceeded actual physician acquisition costs and then marketing these mega-spreads between the physician's acquisition costs and the AWP reimbursement benchmark in order to induce doctors and other providers to buy its drugs based on the drugs' profitability. I find liability for Bristol–Myers Squibb's drugs Taxol (with spreads as high as 500%), Vepesid injectable (with spreads as high as 1,000%), Cytoxan injectable (with spreads as high as 676%), Blenoxane (with spreads as high as 199%), and Rubex (with spreads as high as 438%). The Court finds damages of $183,454 to Class 3. The Court needs additional information to calculate damages for Class 2.

3. *Schering–Plough's* subsidiary Warrick acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for its generic drug albuterol sulfate, which had mega-spreads between 100% and 800% throughout the class period. The Court needs additional information to calculate damages for Class 2.

4. While *Johnson & Johnson's* conduct was at times troubling, it did not rise to the level of egregious misconduct actionable under the Massachusetts Chapter 93A, because its spreads never substantially exceeded the range of what was generally expected by the industry and government.

5. The statute of limitations bars all claims by Classes 2 and 3 before December 1997. When Congress passed the Balanced Budget Act of 1997, it put third party payors on inquiry notice that many AWPs were not true prices paid by physicians and pharmacies to acquire the pharmaceuticals. The class period ends in 2003 when Congress passed the Medicare statute setting new reimbursement benchmarks. Thus, Classes 2 and 3 will include

payments from December 1997 to December 2003.

6. The Court rejects plaintiffs' position with respect to the Medicare Class 2, that defendants acted unfairly and deceptively by having any spread between the published AWP and the true average of prices charged to providers, because the government and industry were well aware by the late 1990's that there was a 20 to 25 percent spread. This discrepancy was tolerated, in part, because of the need to cross-subsidize physician administration costs. Thus, while the spread violated the plain meaning of the Medicare statute, defendants' actions cannot be said to be unfair or deceptive within the meaning of Chapter 93A so long as the spread stayed generally within that expected range.

7. Damages to Class 2 cannot be determined from the current trial record. The Court needs a breakdown of the damages for each drug, using the 30% threshold, for each of the years from 1998 until 2003 for which liability has been found. Defendants may provide their market shares in Massachusetts so that the Court can apportion the damage amount on that basis. If necessary, the Court will hold a damages phase of the bench trial.

The findings of fact and conclusions of law follow.

I. *FINDINGS OF FACT*

A. *The Origins of Average Wholesale Price*

Since the late 1960's, almost every brand and generic prescription drug sold in the United States has had an "average wholesale price," which is published in commercial compendia like Red Book, First DataBank, and Medispan. AWP is used as the basis for drug reimbursement both for drugs administered in physicians' offices ("physician-administered drugs" or "PADs") and for self-administered drugs dispensed by pharmacies ("self-administered drugs" or "SADs"). "Average Wholesale Price" or "AWP" was the pricing benchmark used by the federal government for Medicare reimbursement throughout the class period (1991 to 2003) until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. *See* Pub.L. No. 108–173, 117 Stat. 2066. Throughout this period (and until today), it has also been the pricing benchmark used by most TPPs in Massachusetts and the nation. In 2002, Dyckman & Associates conducted a survey of private health plans regarding their payments for physician-administered drugs and found that all of the plans used a percentage of AWP as a formula to reimburse physicians for these drugs; that most plans used an AWP pricing formula that was in the range of 90 to 100 percent of AWP; and that the average percentage was 98 percent. (Rosenthal Dir. ¶ 26.)

AWP provides a common standard to process millions of drug transactions. A common benchmark is useful because TPPs reimburse for thousands of drugs and services. As the independent court expert Professor Ernst Berndt, a healthcare economist from MIT, stated, AWP is "a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically." (DX 1275, Berndt Report ¶ 23.)

The federal government's Centers for Medicare and Medicaid Services ("CMS") (and its predecessor the Health Care Finance Administration, or "HCFA") do not regulate or set the AWPs, but have entrusted the pharmaceutical companies with the task of reporting the AWPs accurately to the publications. While CMS had the authority to conduct surveys to verify the acquisition costs of providers, it never did

so. The TPPs also rely on the AWPs reported by the pharmaceutical companies to the publications.

Initially, AWP was the average price charged by wholesalers to providers, like doctors and pharmacies. It was derived from the markup charged by wholesalers over their actual acquisition cost, sometimes called the "Wholesale Acquisition Cost" or "WAC." Historically, there was an industry-wide formulaic 20 or 25 percent markup between WAC and AWP. At some point, though, because of consolidation and competition among wholesalers, these standard markups on branded drugs no longer reflected actual wholesaler margins, which were reduced to 2 to 3 percent. Therefore, the actual average wholesale price charged by wholesalers to providers was much lower than the 20 or 25 percent markup over WAC.

Nonetheless, most manufacturers, including AstraZeneca, Schering–Plough, and J & J, continued to report AWPs to the publications based upon the historic formulaic 20 to 25 percent markup, rather than adjusting these prices to reflect the lower, true margins. These manufacturers knew that wholesalers were not actually charging these prices to providers, that the AWP was not a true average of prices charged by wholesalers, and that the "AWP" based on the formulaic 20 to 25 percent markup had become an anachronism. BMS emphasizes that it reported a Wholesale List Price ("WLP") to the publications, rather than an AWP, but it expected—and indeed directed [9]—that the publishing compendia would apply a standard markup to their WLPs to derive an AWP. As such, BMS effectively controlled the AWP published in the compendia. This formulaic markup has never been reduced to reflect actual market conditions.

B. *Medicare Part B*

Medicare is the largest insurer of physician-administered drugs. During the class period, there were approximately 450 covered drugs reimbursed by Medicare Part B.[10] Medicare Part B covers professional services, including those drugs that were "incident to" a physician's services, drugs administered with durable medical equipment ("DME"), and drugs specifically covered by statute. These specialty drugs are typically administered by physicians in an office setting or in hospital outpatient departments, the latter being more expensive. Covered drugs also included some self-administered drugs.

For a Medicare Part B covered drug, 80 percent of the cost is paid for by the federal government, and 20 percent is paid for by whoever is responsible for the copayment. *See* 42 U.S.C. § 1395*l*. Many individual Medicare recipients have a private supplemental insurance policy that covers all or part of their 20 percent copayment. In Massachusetts, these TPPs that provide supplemental insurance (sometimes called Medigap insurance) are members of Class 2.

Initially, reimbursement for prescription drugs under Part B in the Medicare program was on a "reasonable charge" basis.

9. *See* PX 183 ("Effective immediately Bristol–Myers Oncology Division products factor used in determining the AWP should be changed from 20.5% to 25%."). Red Book made the requested change.

10. The drugs involved in this litigation represent a tiny percentage of the thousands of pharmaceutical products available in the United States market. In 2002, approximately 3 percent of Medicare's spending was on physician-administered drugs. (DX 1275, Berndt Rep. ¶ 187.) Dr. Berndt estimates that "in 2002, expenditures on physician-administered drugs were likely less than 1.5 percent of national health expenditures, and considerably smaller in earlier years." (*Id.*)

56 Fed.Reg. 25,792 (June 5, 1991). (*See also* Bell T1 Aff. ¶ 78; Hartman Decl. ¶ 12.) Prior to 1992, Medicare's carriers used the customary or prevailing charge among physicians in a geographic area. (*See* Bell T1 Aff. ¶ 78.) In June 1991, HCFA proposed changing reimbursement to the lower of 85 percent of AWP or estimated acquisition cost ("EAC"), as determined by HCFA through surveys. Based on comments from doctors that they could not procure many drugs at that level of reimbursement and that there were shortfalls in chemotherapy administration payments, HCFA backed off this proposal. (*Id.* ¶ 80.) Instead, it adopted reimbursement for PADs under Part B at the lower of AWP or EAC (plus an allowance for other costs), effective January 1, 1992. (*Id.* ¶ 81.) The EAC could be determined based on a survey of physicians or actual invoice prices paid by physicians for the drug. 56 Fed.Reg. 59,502 (Nov. 25, 1991).[11]

Unfortunately, Medicare carriers did not conduct surveys of actual invoices, and took the shortcut of reimbursing based on AWP. On one occasion, when one carrier attempted to base reimbursement on physician acquisition costs, HCFA actually directed the carrier *not* to collect invoices from physicians in order to implement an acquisition cost survey. (Bell T1 Aff. ¶ 84.)

Effective January 1, 1998, pursuant to a statutory change, the Medicare regulations were amended so that the allowed amount would be based on the lower of the billed charge or 95 percent of AWP. *See* 42 C.F.R. § 405.517 (1999) (Department of Health and Human Services ("DHHS") Regulations); *see also* 42 U.S.C. § 1395u(*o*) (Medicare statute). Significantly, there is no statutory or regulatory definition of AWP.

Up until 1998, multi-source drugs[12] were reimbursed at the lower of the estimated acquisition cost or the "median price for all sources of the generic form of the drug." 56 Fed.Reg. at 59,621 (DX 1049). Since 1998, multi-source reimbursement has been set at the lower of the billed charge or 95 percent of an average wholesale price, defined to be the lesser of the median generic AWP and the lowest brand name product AWP. 42 C.F.R. § 405.517 (2003) (DX 1852); *see* 42 U.S.C. § 1395u(*o*).

C. *Manipulating and Marketing the Spread*

The use of AWP as an embedded pricing benchmark used by the federal government, state governments,[13] and private insurers alike created perverse incentives for the drug manufacturers and the physicians. Typically, a single-source drug[14]

11. HCFA stated:

> Estimated acquisition costs would be based on individual carrier estimates of the costs that physicians, or other providers as appropriate, actually pay for the drugs. Carriers could survey a sample of the physicians who furnish the drugs to obtain cost information. As an alternative, carriers could request that physicians periodically provide cost information when they submit claims for payment for the drugs.

56 Fed.Reg. at 59,502.

12. Multi-source drugs are drugs that no longer have patent protection so that several manufacturers can produce generic versions of the drug.

13. Most states use AWP (or its formulaic counterpart WAC) as the pricing benchmark for Medicaid as well.

14. A single-source drug is a drug that is under patent protection and produced by one manufacturer, so that there are no competitors producing generic versions of the drug. However, some single-source drugs face therapeutic competition from drugs that have different chemical compositions, but can be used for the same indication.

without therapeutic competition bore a predictable relationship to acquisition costs. (Bell T1 Aff. ¶ 6.) When a branded drug faced competition from a therapeutic equivalent, though, the drug manufacturer could manipulate the spread—the difference between the actual selling price and the AWP based reimbursement—to make the drugs more attractive to a physician. The manufacturer could then "market the spread" to the physician to increase sales and market share.

To fully understand the strategy of manipulating and marketing the spread, one needs to understand that physicians purchase drugs in essentially three ways. The first route is a direct sale from the manufacturer to the provider of physician-administered drugs. AstraZeneca's Zoladex is one example of this direct distribution chain. In these instances, the doctor purchases the pharmaceutical from the manufacturer and bills the TPP, making a profit on the difference between the acquisition cost and the reimbursement amount. When there is therapeutic or generic competition, some providers may be "preferred purchasers" from a manufacturer's perspective and be able to acquire the pharmaceutical at a lower price, increasing the spread.

The second route is an "indirect" path, which involves a sale by the manufacturer to an intermediary such as a wholesaler or specialty distributor that provides services, like refrigeration and overnight delivery, needed to deliver perishable biologics and pharmaceuticals. (Bell T1 Aff. ¶ 10.) As Dr. Bell describes it:

> Due to the intermediary mark-up, in instances of indirect distribution, the provider often purchases the pharmaceutical at a wholesale price that is higher than the price paid to the manufacturer by the specialty distributor or wholesaler. Some of the ultimate physician or hospital purchasers, however, may be preferred providers from the manufacturers' perspective. The manufacturers compete for their business by offering a lower price for the pharmaceutical. The preferred provider receives such a lower price either through a chargeback (the provider purchases the product at the lower price from the specialty distributor or wholesaler who then "charges back" the amount of the price concession to the manufacturer) or a rebate (a price concession provided by the manufacturer directly to the provider).

(*Id.* ¶ 11.)

A third route of distribution involves the sale by a drug manufacturer to a specialty pharmacy which takes title to the pharmaceutical. The physician bills the TPP for administering the drug and the specialty pharmacy bills for supplying it. This last method of distribution was rare during the class period.

Whether doctors purchased the drugs directly from manufacturers or indirectly through wholesalers or specialty distributors, they had to seek reimbursement for the drugs from the TPPs and Medicare Part B. During the class period, TPPs typically did not use pharmacy benefit managers ("PBMs") or consultants to negotiate drug prices with doctors and did not use formularies to control drug costs. Typically, the government and private insurers reimbursed for whatever drugs the doctor prescribed because of the serious nature of the diseases, especially cancer—a target of many of the drugs in this case. When a drug was a single-source pharmaceutical with no therapeutic competition, the doctor had little leverage over pricing. However, when there was therapeutic competition with another branded drug or a multi-source PAD, the physician had huge leverage over price because she con-

trolled the prescription of the drug and could choose which drug to administer.

Knowing that the doctor played this key role, the drug manufacturers launched sales forces directly into the doctors' offices to negotiate drug pricing. Significantly, for this case, the terms of the contracts were kept confidential.[15] Rather than marketing simply the therapeutic qualities of the drug, many in the pharmaceutical sales force nimbly marketed the "spread" (also called the "margin" or "return to practice") between what the doctor paid for the drug and what she would be reimbursed.

A pharmaceutical company manipulated the spread in two ways. Sometimes, it would raise the AWP reported to the publishing company, which would increase the spread. The manufacturer would either report an AWP or report a wholesale acquisition price, also called a direct price or list price, with the expectation that the publishing company would apply the formulaic markup to determine the AWP. Thus, all else being equal, physicians would have an incentive to select a product with a larger spread, even if the acquisition cost of that drug exceeded that of a therapeutic substitute. This was also a cost-free approach from the manufacturer's point of view, as raising the AWP did not diminish its profit margin on the drug. Sometimes, the pharmaceutical manufacturer would increase the spread by providing the doctors with rebates, chargebacks, discounts, or free samples, which would decrease the actual acquisition cost of the drug. This approach, of course, results in less income to the manufacturer. A helpful metaphor is a pair of scissors: the spread could be increased by raising the top blade (the AWP) or lowering the bottom (the acquisition cost), or both. This "spread" existed regardless of whether the drug was reimbursed by Medicare or TPPs which, as discussed above, typically predicated contractually-based reimbursements on AWP.

During the class period, many doctors (particularly oncologists and urologists) eagerly entered the fray by exacting discounts and rebates from manufacturers. Many doctors purchased the drugs based on their "return to practice," which means the profitability of the drug to the practice. Some physicians had significant marketing leverage because of the nature of their specialties, geographic location, and reputation. The doctor would pay a discounted price for the drugs, and seek the much higher reimbursement amount from the government and TPPs. Medicare required that the doctors charge the Medicare patients their 20 percent co-payment based on AWP. Despite knowing that their acquisition cost was much lower than the published AWP, the doctors charged patients a co-payment based on this inflated AWP. Doctors, however, could not always collect the entire co-payment from those patients who were unable to pay, and therefore they had to absorb that loss of reimbursement. Also, some doctors did not charge Medicare beneficiaries who could not afford the coinsurance payment. Many third-party payors also required beneficiaries to make percentage coinsurance payments.

Plaintiffs' expert Professor Meredith Rosenthal, a health care economist who teaches at the Harvard School of Public Health, explains why there was no competitive pressure on doctors to lower the

15. Indeed, throughout this litigation these contracts were marked "highly confidential" pursuant to a protective order.

prices of drugs they charged to TPPs and patients:

> As professionals, physicians command a large amount of technical and clinical information that is not accessible to patients or payers who can only imperfectly judge whether a physician is making appropriate diagnoses or treatment choices. Such asymmetric information about the nature of the service being delivered poses problems for price competition because patients and payers are unable to make "apples to apples" comparisons of providers—that is, to compare prices for services of equal value. This asymmetry of information, along with the high stakes involved (health), also leads to the importance of trust in physician-patient interactions. Trust, in turn, limits the substitutability of physicians from a given patient's perspective. This perceived differentiation of physicians on the basis of trust weakens price competition, particularly when the patients concerned are acutely or chronically ill as are most recipients of the physician-administered drugs now at issue.

(Rosenthal Dir. ¶ 30.) Because there was little or no payor oversight of the physician's choice of drug, doctors had no incentives to lower prices. (Hartman Decl. ¶¶ 108–09.)

Professor Rosenthal also described the economic incentives for pharmaceutical manufacturers:

> For class drugs, the relevant measure of the financial consequence of choosing a particular physician-administered drug is the difference between the reimbursement for the drug, which is a function of AWP, and the acquisition cost of the drug to the physician or clinic. This means, as is true in other markets, that manufacturers can increase their market share by reducing the cost of their product to physicians through discounts or rebates. But the unique and perverse feature of this market is that pharmaceutical manufacturers can also increase market share through raising their AWP, since this list price is the basis for third-party reimbursement. Unlike offering big discounts to physicians, raising the AWP relative to the acquisition cost to the physician does not reduce profit margins on the drug in question.

(Rosenthal Dir. ¶ 33.)

The paradigm case of "marketing the spread" involves the marketing battle between Zoladex and Lupron, both used to treat prostate cancer. An AstraZeneca document sums up this motivation with respect to the sale of Zoladex: "As we have come to understand in our experience with Zoladex, urologists are motivated by economics.... Zeneca has learned that in order to compete in [a] market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice.'" (PX 14 at 7143.)

D. *Cross–Subsidization*

One oft-cited justification for inflating the AWP above true market costs is that reimbursement for the physician services rendered in administering the drugs often fell short of the costs of administration incurred by the physicians. (Bell T1 Aff. ¶ 7.) For example, CMS acknowledged that "Medicare payments related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate." (DX 1090 at 0059.) Accordingly, doctors used the profit margin on the drugs to cross-subsidize administration fees and other risks (like spoilage) associated with physician-administered drugs. (Bell T1 Aff. ¶ 75.) At trial, there was no evidence about the extent of a shortfall in the costs of administration of the drugs in question in this

litigation. Moreover, there was no evidence that any margin over the 20 to 25 percent industry-wide formula was needed to compensate doctors for their costs of administration for these drugs and risks like spoilage. Significantly, the pharmaceutical companies marketed the spread by demonstrating to the doctor that he would make a profit on the drug, not by demonstrating that the drug would cover costs of administration or other risks.

E. *Patient, The Vulnerable Victim*

Disturbingly, the patient was a vulnerable victim of this strategy of "marketing the spread" because when the AWP was raised, the Medicare patient was required to make a co-payment of 20 percent of the inflated AWP (or AWP–5% after 1998). The manufacturers understood well the harmful impact that publishing inflated AWPs had on the elderly cancer patient. For example, Mr. Buckanavage of AstraZeneca testified as follows:

> THE COURT: Excuse me. Did you understand that Medicare beneficiaries paid 20 percent of AWP?
>
> THE WITNESS: Yes. They paid 20 percent out of pocket.
>
> THE COURT: So you understood that every time you raised AWP, they had to pay 20 percent of the increase?
>
> THE WITNESS: Yes. Whenever we took a price increase, it would raise the copay and also raise the reimbursement.

(11/14/06 Tr. 13:2–10 (Buckanavage).)

Beneficiaries of private insurers also had to make higher percentage co-payments. Not surprisingly, none of the cancer patients who testified had ever heard of AWP, and they trusted their doctors to pick drugs for them based on effective treatment criteria, not profitability. (*See, e.g.*, 11/07/06 Tr. 74:13–15, 75:20–76:1 (Choice); 11/07/06 Tr. 101:9–16, 107:23–25 (Hopkins).)

The pharmaceutical companies were aware of the political ramifications if the impact of raising AWPs on patients became publicly known. For example, on January 2, 1998, in response to an inquiry about a government report on drug reimbursement, Cathleen Dooley of J & J's subsidiary OBI acknowledged in an email:

> By law, the physician must bill the patient the remaining 20% copay.... This will be a sensitive issue because the physician is able to bill Medicare and the patient off of AWP; the patient's 20% copay is higher than it would be if it was billed off of acquisition cost (*public relations issue*).

(PX 259 (emphasis added).) In addition, pharmaceutical manufacturers understood that this strategy had the effect of inducing doctors to prescribe a drug at least partly based on return to practice rather than just on the therapeutic quality of the drug.

The pharmaceutical companies made some attempts to deal with the public relations issue. Many manufacturers instituted programs to help patients make the co-payment.[16] Two companies eventually instituted internal ethical guidelines to ban

16. *See, e.g.*, Black Decl. ¶ 6 (explaining AstraZeneca's Patient Assistance Program which provided products to economically disadvantaged patients free of charge); Kane Decl. ¶¶ 23–24 (explaining Schering's "Commitment to Care" and "SP Cares" programs which provide free drugs to qualified low income patients); 11/16/06 Tr. 25:15–26:16 (Dooley) (explaining J & J's patient assistance program that helped low income patients pay for their portion of drug costs); 11/14/06 Tr. 115:19–117:19 (Hoffman) (explaining that Centocor provides free Remicade to patients with incomes of 300% or less of the federal poverty level); Pasqualone Aff. ¶ 22 (explaining BMS's "ProCert" program which provided reimbursement assistance to health care providers).

marketing the spread. In January of 2001, BMS sent a memo to all U.S. Sales & Marketing Personnel advising that, "in accordance with its Code of Conduct, . . . the spread should not be used as a promotional or marketing tool." (PX 223.) Later that year, Ortho Biotech, a subsidiary of J & J, sent a memo to its sales force stating: "It is absolutely inappropriate to sell product based upon the difference between AWP and acquisition cost." (DX 2767.) What was remarkable, though, was how few of the pharmaceutical witnesses at trial were concerned about the impact of an inflated AWP on old and sick people making co-payments based on a percentage of AWP. Indeed, from the vantage point of AstraZeneca's sales team, they were actually assisting patients because Zoladex was cheaper than Lupron in treating prostate cancer.

F. *Self–Administered Drugs*

Some of the Medicare Part B drugs are self-administered and primarily dispensed by pharmacies. Examples are Temodar, a single-source drug manufactured by Schering–Plough, and albuterol, a multi-source generic manufactured by Schering–Plough's subsidiary Warrick. Retail pharmacies have little ability to determine which single-source drugs will be dispensed to a patient, because they must dispense whichever drug is prescribed by the physician. Pharmacies therefore receive few price concessions on single-source drugs.

With respect to generic drugs, though, pharmacists determine which manufacturer's version of a multi-source drug will be sold. Generic manufacturers thus compete on price so that a pharmacy or pharmacy chain will stock their version of a generic drug. However, Medicare generally reimburses multi-source drugs at 95 percent of the median of the generic AWPs. In private contracts, TPPs typically impose a maximum allowable cost ("MAC") or other limit to curtail costs.[17] Thus, in Class 3, TPP reimbursement for multi-source drugs is generally not calculated based on the drug's AWP. Accordingly, no damages have been calculated for multi-source drugs in Class 3.[18]

G. *Knowledge in the Industry*

At least since the start of the class period, the most knowledgeable industry insiders, like the larger TPPs, including Blue Cross/Blue Shield of Massachusetts ("BCBSMA"), the named plaintiff, came to understand that with respect to self-administered drugs, like pills, the AWP of the pill did not reflect the actual average price charged by wholesalers to retail pharmacists. Knowledge about the AWP of SADs was available in the industry largely because of the role of the PBMs, which represent TPPs in negotiating drug prices with pharmaceutical manufacturers to get discounts and rebates on SADs sold by pharmacies.[19] There were also commercial data services like IMS Health

17. Although AWP can influence MACs, most MACs are proprietary and the specific formulas that are used to develop those MACs are unknown. (11/15/06 Tr. 119:7–120:4 (Rosenthal).) Dr. Hartman assumes that the MACs are not based on AWP. (Hartman Decl. ¶ 155(b).)

18. For single-source drugs that lose patent protection, Dr. Hartman continues to calculate damages for six months after the first generic launch. At that point he assumes that multiple generic launches occur and MAC pricing is used. (Hartman Decl. ¶ 155(a).)

19. The important role of PBMs in the area of self-administered drugs is described at length in the memorandum on class certification. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71–73 (D.Mass. 2005).

which published marketing data. With these SADs, institutions like TPPs exercised control over physician prescribing patterns through formularies, and secured discounts from manufacturers selling competing single-source and multi-source drugs. (Bell T1 Aff. ¶ 39.) Moreover, as Dr. Bell points out, some TPPs were vertically integrated, running staff model health maintenance organizations ("HMOs") which purchased SADs. In this way, they learned that the AWP of the drug was not the price of acquisition.

Information about the pricing of physician-administered drugs was far more opaque. The contracts *required* that all pricing terms be kept confidential. PBMs were not involved, and there was no standard published commercial transaction data for PADs available to TPPs. As such, industry experts, TPPs, academics, and the government typically did not have information as to the price paid by the doctors to acquire the drugs. While some TPPs had staff model HMOs which purchased PADs, knowledge about discounts given to bulk purchasers like HMOs did not provide a transparent picture of average prices charged to other classes of trade like physicians or physician groups. (*See* Bell T1 Aff., App. C (describing vertical integration in drug purchasing); *see, e.g.*, DX 1630 (1993 Los Angeles Times article reporting that Rite Aid complained in 1993 that HMOs and other classes of trade received better prices than drugstores).)

H. *Mega–Spreads*

To recap, throughout the class period, most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup. In addition, payors were aware there was some discounting from WAC. However, I find that in the early 1990's, payors typically did not understand that there were mega-spreads far in excess of the formulaic markup for physician-administered drugs when there was competition between therapeutic equivalents or multi-source drugs. Indeed, the named plaintiff TPPs had no knowledge or expectation as to the size of the spreads available to physicians.

Plaintiffs' expert, Dr. Raymond S. Hartman, a healthcare economist, testified that the marketplace had an expectation that AWP did not exceed the average sales price by more than 30 percent.[20] (Hartman Decl. ¶ 77(a)-(c).) After reviewing studies produced by government offices, as well as academic and popular publications between 1992 and 2004 for PADs, he concluded that "the publicly available survey evidence generally informing the government, policy makers, and industry participants about spreads on single-source physician administered drugs over much of the Damage Period suggested that the spreads were not excessive." (Hartman Decl. ¶ 77(c); *see also* Hartman Rebuttal ¶¶ 46–47.)

By the mid–1990's, information about the existence of mega-spreads began to seep into the marketplace. For example, on June 10, 1996, Barron's published an article titled *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?* describing AWP as "Ain't What's Paid." (*See* DX 2641.) It stated that for "many drugs, especially the growing number coming off patent and

20. Dr. Hartman refers to this expectation that AWP exceeded ASP by 30 percent as his "expectations yardstick." Dr. Hartman uses the yardstick to find liability whenever a drug exceeds that threshold. This expectations yardstick is explained in detail in the Conclusions of Law, *infra*.

going generic, the drug providers actually pay wholesale prices that are 60%–90% below the so-called average wholesale price, or AWP, used in reimbursement claims." (*Id.* at 15.) In Dr. Hartman's calculations, these are spreads of 150% to 900%. The Barron's article reports on a doctor having a plaque reading "This is the house that leucovorin [21] built." (*Id.*) The article also included a chart showing spreads for a number of the drugs in this litigation. The chart listed Doxorubicin (Rubex) as having a spread of 72% off AWP (Hartman spread of 271% above average sales price) and Etoposide (Vepesid) with a spread of 76% off of AWP (Hartman spread of 316% above average sales price). (*Id.*) There was a growing sense among doctors, TPPs, and others that AWP stood for "ain't what's paid."

Less sophisticated participants, like Taft–Hartley Plans, which are union benefit funds, still did not understand that AWP was not a true market average because there was so much misinformation in the market. For example, in promoting its AWP price data, First DataBank, one of the major publishers, stated that AWP "is the average wholesale price. That is, AWP is the average of the prices charged by national drug wholesalers for a given product (NDC)." (DX 1275, Berndt Rep. ¶ 78.) This information was available on the website of the American Society of Consultant Pharmacists as late as 2005.(*Id.*)

By 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the compelling information collected by the HHS Office of Inspector General ("OIG"). In addition, the press began to report on the rampant abuse of the AWP system.[22]

I. *The Government Pit Bull*

Initially, the government's concern about the accuracy of AWPs focused on self-administered drugs. A 1984 OIG report involving self-administered drugs stated:

> AWP cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices.

(DX 1039 at 10,206; *see also* DX 1985 at 20,255 (HCFA administrative decision in 1989 stating "AWP was not the price generally and currently paid by providers").)

In 1992, the OIG began to focus on the shortcomings of AWP as a reimbursement benchmark for Medicare physician-administered drugs. The report stated: "Our review of invoices revealed that the 13 chemotherapy drugs can be purchased at amounts below AWP." (DX 1053 at 5.) The OIG listed discounts off of AWP on a number of PADs, including, for example, discounts off of Doxorubicin (Rubex) of 56% to 59%, which are equivalent to spreads of 127% to 144%. (*Id.* at App. III.) Some of the drugs analyzed are at issue in this case, including Bleomycin (Blenoxane), Cyclophosphamide (Cytoxan), Doxorubicin (Rubex), and Etoposide (Vepesid). The OIG concluded: "AWP is not a reliable indicator of the cost of a drug to physicians." (*Id.* at 11.) In 1996,

21. Leucovorin is a cancer drug, not at issue in this trial, that was highly profitable to physicians under the AWP system. (*See* DX 2641 at 15.)

22. *See* Bell T1 Aff. App. B (listing articles in The New York Times, Wall Street Journal, Boston Globe, and other popular press).

it issued another report, examining the possibility of using the Medicaid Best Price rebating approach as a way to save money in the Medicare program. (*See* DX 1062 at 7.) Again, it flagged excessive pricing for Zoladex, Paraplatin, Taxol, Vepesid, Rubex, and Etopophos although it did not calculate a spread. (*See id.*)

Congressional committees also began to examine problems with the AWP system. In June 1997, prior to the passage of the Balanced Budget Act of 1997 ("BBA"), which inserted AWP into the Medicare statute, the Committee on the Budget of the House of Representatives issued a report stating:

> The Inspector General for the Department of Health and Human Services has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals. *For example, the Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs.*

(DX 1071 at 1354 (emphasis added).)

In December 1997, shortly after Congress decided to lower drug reimbursement to 95% of AWP, the OIG issued another report: "[P]ublished AWPs ... bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for these drugs.... We believe that the 5 percent reduction [off of AWP] is not a large enough decrease.... [W]e've identified [spreads of] 11 to 900 percent...." (DX 1075 at ii-iii.)

At about the same time, President Clinton referred to AWP as a "sticker price" in his nationwide radio address: "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system.... [T]hese overpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price, for drugs." (DX 1074 at 2033–34.)

In 1999, Donna E. Shalala, the Secretary of the Department of Health and Human Services reported to Congress:

> For the past 13 years, the Office of Inspector General (OIG) has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than the AWP. To address this problem, the President's 1997 budget contained a legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost (AAC) for the drug of the physician or supplier billing Medicare. However, as discussed above, in the BBA, Congress rejected this proposal in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of AWP.

(DX 1080 at 1–2.) She pointed out that "AWP is not a well-defined concept nor is it regulated in any way," and concluded that AWP bore "no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace." (*Id.* at 2, 8.) A 1999 Medicare Bulletin flagged this awareness that AWP is "not a true discounted price and, therefore, does not reflect the cost to the physician or supplier rendering the drug to the Medicare beneficiary." (DX 1166.)

Professor Ernst Berndt, the Court's independent expert, explained that governmental inertia in fixing the problem of the inaccuracy of the AWP can be explained by the fact that drug expenditures were

not a large portion of healthcare costs. (DX 1275, Berndt Rep. ¶ 187.) This inertia reflected the principle of "the importance of being unimportant." (*Id.*)

Between 1998 and 2002, though, there was rapid growth in Medicare Part B expenditures, particularly with respect to amounts paid as drug expenses to oncologists and urologists due to drug product price increases at the manufacturer level and increases in utilization. According to a report cited by Professor Rosenthal,

> The vast majority (77%) of the Medicare part B drug expense is paid to oncologists and urologists. Oncologist-based drug expenditures grew from $1.2 billion in 1998 to $3.8 billion in 2002 with the spending growth from 2001–2002 at 41 percent. The spending on drugs under Medicare Part B is highly concentrated with 7 of the approximately 450 drugs accounting for 49 percent of the spending ($4.0 billion out of the $8.4 billion).

(Rosenthal Dir. ¶ 22.)

In 2000, the Department of Justice ("DOJ") compiled and reported actual average wholesale prices—the prices at which the wholesaler sells the drugs—for approximately 400 National Drug Codes ("NDCs")[23] covered by Medicare. (*See* DX 1091 at 1.) The DOJ indicated that "these are more accurate wholesale prices for these drugs." (*Id.*) Plaintiffs, in their complaint, calculated the spread between the DOJ's actual AWP and the published AWP for many of the drugs in this litigation. (*See* Compl. ¶¶ 65, 112.) Several of those spreads exceed 100%. (*See id.*)

HCFA again attempted to administratively change reimbursement from an AWP basis to the cost-based prices calculated by the DOJ, (*see* DX 1091), but various members of Congress urged it to reconsider, primarily because of concerns that oncologists were being underpaid in administering their services, and that this underpayment needed to be corrected before reducing reimbursement. (*See* DX 1085 (letter to Secretary Shalala from Congress members); DX 1086 (same); DX 1090 (HCFA letter announcing the change).) The senators seemed particularly perturbed because "the Department's unilateral declaration of a new definition of AWP, with no regulatory process, is inappropriate." (DX 1086 at 2.)

After HCFA retracted its authorization regarding the use of these new AWPs in November 2000, Congress passed the Benefit Improvement and Protection Act of 2000, which prohibited the Secretary of HHS from implementing any payment reduction for drugs until the Government Accountability Office ("GAO") prepared, and the Secretary reviewed, a report on revised payment methodologies for drugs. (Bell T1 Aff. ¶ 89.) In September 2001, the GAO released its report which found that: (1) the average discount from AWP for physician-administered drugs ranged from 13% to 34%, equating to "spreads" of 15% to 52%; (2) two physician-administered drugs had discounts of 65% and 86%, equating to "spreads" of 186% and 614%; and (3) two drugs used with durable medical equipment had discounts of 78% and 85%, equating to "spreads" of 355% and 567%. (*Id.*)

Like a pit bull, OIG pursued the AWP issue. In 2003 it issued a Compliance Program Guidance for pharmaceutical manufacturers, which admonished:

23. Every drug has a unique identifying 11-digit number called an NDC. The first 5 digits identify the firm marketing the drug, the next 4 digits identify the specific strength, dosage form, and formulation of the product, and the final 2 digits identify the package size and package type. (DX 1275, Berndt Report ¶ 192.)

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. *The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.* Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

68 Fed.Reg. 23,737 (May 5, 2003) (emphasis added) (PX 4016). This was the first written guidance from the government addressing marketing practices related to AWP.

J. *The Demise of AWP as Government Pricing Benchmark*

Finally, ten years after the OIG first reported the deficiencies in using unregulated AWPs as reported by the pharmaceutical industry as the benchmark for Medicare reimbursement, Congress took action with the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") with an effective date of December 8, 2003. *See* Pub.L. No. 108–173, 117 Stat. 2066. The MMA provided for a shift from 95% of AWP to 85% of AWP in 2004 and then to 106% of "average sales price" [24] in 2005. *See* 42 U.S.C. § 1395u(*o*). The class period ends the day the MMA went into effect. On April 6, 2004, CMS issued a detailed interim rule on how manufacturers should calculate ASP data on Medicare Part B drugs. The final rule was issued on September 16, 2004. Reimbursement based on ASPs took three years to implement because the government not only had to determine the methodology for calculating the ASP, but also had to ascertain the amount needed to increase service fees for oncologists and other physicians administering drugs.

Even with the increase in administration fees paid to doctors, Medicare has had overall cost savings from the decrease in drug expenditures for Zoladex, Taxol, Remicade, Procrit, and albuterol.[25] The

24. The statute defines "average sales price" as "the manufacturer's sales to all purchasers" divided by "the total number of such units of such drug or biological sold by the manufacturer." 42 U.S.C. § 1395w–3a(c)(1). The average sales price "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates...." *Id.* § 1395w–3a(c)(3).

25. Dr. Gaier argues that the results under the MMA are inconclusive and introduced a graph demonstrating that the annual percent-

total reimbursement for a typical administration of Zoladex, including both product cost and administration fee, fell from $451.56 in 2002 to $226.48 in 2005 under the new ASP system. (PX 4069.) Looking at those same two years, the cost of a typical dose of Taxol dropped from $1785.16 to $428.07 (PX 4070), Remicade from $2,035.15 to $1,703.09 (PX 4071), Procrit from $150.65 to $131.96 (PX 4072), and albuterol from $109.74 to $71.63 (PX 4095).

Medicare Reimbursement under the MMA

	2002	2005	Savings
Zoladex	$ 451.56	$ 226.48	49.9%
Taxol	$1785.16	$ 428.07	76.0%
Remicade	$2035.15	$1703.09	16.3%
Procrit	$ 150.65	$ 131.96	12.4%
albuterol	$ 109.74	$ 71.63	34.7%

(*See* PX 4069; PX 4070; PX 4071; PX 4072; PX 4095.)

Dr. Rosenthal's review of the hard data, as laid out above for several drugs in this case, shows that "the overall dollar reimbursement declined for each drug." (Rosenthal Rebuttal ¶ 15.)

Despite the *Sturm und Drang* from some medical providers, doctors have not generally shifted their patients to a more expensive hospital setting. According to a July 13, 2006 MedPAC report, the MMA "payment changes did not affect beneficiary access to chemotherapy services." (PX 4019 at 5.) "Physicians provided more chemotherapy services and more Medicare beneficiaries received services in 2005 than in 2004." (*Id.*)

K. *Stuck*

To date, TPPs have generally not shifted away from the AWP benchmark despite likely cost savings. On February 7, 2004, BCBSMA, the class plaintiff, did a study demonstrating that a shift would save them $6,010,576 even with the increase in administration fees. (DX 990 at 12.) As reasons for reform, BCBSMA states:

- Physicians benefit from the "spread" between AWP and acquisition cost creating an overpayment for drugs and costs for Medicare
- According to GAO and CMS, in 2001 Medicare overpaid Part B drugs by over $1 billion.
- In 2002 oncologists collected approximately $600 million in overpayments.
- Patients who pay a coinsurance are adversely affected by the inflated AWP.

(*Id.*) But BCBSMA was afraid that its network of doctors would rebel at lower reimbursement rates: even if service fees went up, doctor profitability would go down. Cautious and fearful, BCBSMA decided not to follow Medicare and to continue using AWP as the pricing benchmark. Indeed, it recently decided to employ AWP in its fee schedule with hospitals, a different class of trade. As of the date of the trial, only a few TPPs have shifted to an ASP system. United Healthcare moved to ASP-based pricing, but chose to reimburse at ASP plus 12 percent for oncologists only. (Bell T1 Aff. ¶ 37.)

Defendants highlight the failure of TPPs to react when the mega-spreads became well known. It is hard to understand why the TPPs did not decrease the percentage off AWP during the five years after 2001 when knowledgeable TPPs typically understood that there were mega-spreads between cost and reimbursement prices, in

age growth in Medicare Part B expenditures per beneficiary have increased in 2004 and 2005. (11/29/06 Tr. 21:2–22:10 (Gaier); DX 1496.) While he believes that graph is "evidence that the overall Medicare Part B expenditures are going up," Dr. Gaier concedes that he doesn't have the data to analyze why that is happening and acknowledges that there are a variety of possible reasons. (*Id.* 21:15–23:8.)

excess of any reasonable compensation for service fees or risks (like spoilage or shelf life). While TPPs likely shut their eyes to the 20 to 25 percent spread to permit cross-subsidization of physician costs, the new Medicare structure provided an alternative reimbursement scheme. (*See* Bell T1 Aff. ¶¶ 77–92 (explaining Medicare's assumption that drug reimbursement would cross-subsidize other costs).) This diffidence can no longer plausibly be explained by the "importance of being unimportant," since drug costs had increased substantially over the class period.

Remarkably, BCBSMA, the behemoth insurer in the Massachusetts market, and other large TPPs, were not proactive in adjusting to cost data once Medicare did the legwork for them in devising more reasonable drug pricing and service fees. Medicare provided the TPPs with cover, by insulating them from protests by the network of providers. Dr. Rosenthal explains this inertia as "stickiness," which is the economists' label for the common sense phenomenon that it is much harder to decrease reimbursement rates than to increase them. TPPs were worried that they risked either losing network providers or pushing patients into the more expensive hospital setting if they pressed for lower AWPs on individual specialty drugs.

L. *The Plaintiffs/TPPs*

1. Blue Cross/Blue Shield: Class 2 and Class 3 Representative

Plaintiff BCBSMA, a class representative for both Class 2 and Class 3, provides health coverage for approximately 2.5 million lives in the State of Massachusetts. (11/7/06 Tr. 147:2–3 (DeVaux).) BCBSMA is currently the state's largest health insurance company with over 4,000 employees and covering approximately 46% of the covered lives in Massachusetts. In 2005, BCBSMA paid $9.4 billion in claims. It has made payments for single-source drugs manufactured by each defendant in both Class 2 and Class 3, and in the case of multi-source drugs, has purchased a drug with a J-code [26] that matches a J-code of a drug manufactured by a defendant. (*See* PX 4012; Mulrey Aff. ¶¶ 20–22.)

Currently, BCBSMA primarily uses a fee-for-service arrangement with its physicians and physician groups, though it has also used capitated [27] and other risk sharing arrangements. (Mulrey Aff. ¶ 5.) Under the fee-for-service arrangement, BCBSMA establishes a fee schedule that governs provider reimbursement for the purchase and administration of drugs. (Devaux Aff. ¶ 7.) These fee schedules are contained in the contracts between BCBSMA and the physician or physicians group. (DeVaux Trial Aff. ¶ 8.)

From 1991 until 1995, the reimbursement amounts in the fee schedules were based on the usual and customary charge for the particular drug. (Mulrey Aff. ¶ 10.) Therefore, BCBSMA has no claim for Class 3 damages prior to 1995. In 1995, BCBSMA first began using AWP as

26. CMS established the Health Care Common Procedure Coding System ("HCPCS") which provides 5 digit J-codes to be used for billing injectable drugs. (*See* DX 1275, Berndt Report ¶ 193.) For multi-source drugs, multiple NDCs for drugs sold by various manufacturers are reimbursed under the same J-code. (*See id.*)

27. Some private insurers pay physicians for drugs on a capitated basis, i.e., the physician and the plan negotiate over a drug budget for each patient, with the physician bearing the risk that payments received may not be adequate to cover his other costs of services provided. (Bell T1 Aff. ¶ 67.) This lawsuit does not cover these capitated agreements. Dr. Hartman's damage assessment excludes any reimbursements unrelated to AWP.

a basis for reimbursement to physicians for PADs. (*Id.* ¶ 11.) From 1995 to 1998, BCBSMA used 100% of AWP as the basis for reimbursement of PADs, and in 1998, BCBSMA moved to using 95% of AWP. (*Id.*) Until 2005, BCBSMA obtained the AWP it used for these fee schedules from Medicare. (*Id.* ¶ 12.) Fee updates would be retrieved from Medicare/NHIC websites or the Medicare B Resource guide. (*Id.*)

In the Medicare context, BCBSMA offers Medex plans which are "MediGap" plans that cover a Medicare Part B beneficiary's 20 percent co-payment. (Arruda Aff. ¶ 3.) BCBSMA has approximately 160,000 individuals who purchase these Medex plans directly, and approximately 85,000 individuals who receive the coverage through a group sponsored plan. (*Id.* ¶ 4.)

At trial, Kenneth Arruda, a BCBSMA marketing executive, explained that Medex premiums were set based on the prior two years' claims experience by calculating projected benefit costs, expected administrative expenses, and a contribution to reserves. (11/08/06 Tr. 133:6–22, 154:25–155:3 (Arruda).) The contribution to reserves is an additional 2.5% of the premium that is added to cover shortfalls from miscalculation, increased utilization due to mass illness, previously unreported claims, and other unforeseen needs. (*Id.* 135:18–136:19, 137:11–14.) Mr. Arruda explained the need for the contribution to reserves: "This is generally a risky business because [we] are covering people who are over age 65 who have severe and in some cases catastrophic health care needs." (*Id.* 136:17–19.)

Up until 1996, BCBSMA owned a staff model HMO, Medical West, Inc. (Coneys Aff. ¶ 13.) Medical West, Inc., comprised of Medical East and Medical West Health Plans, had several clinics located throughout Massachusetts. Medical West, Inc. operated an in-house pharmacy that provided PADs to physicians. (*Id.* ¶ 8.) Medical West, Inc. negotiated directly with drug manufacturers to purchase drugs for this pharmacy. (Curran Aff. ¶ 15.) According to the testimony of defense expert Eric Gaier, the staff model HMO purchased drugs at discounts as high as 92.6% below AWP, which under Dr. Hartman's calculation is a spread of over 1200%. (Gaier Aff. ¶ 34; *see* DX 1389–DX 1403.)[28]

One fact dispute is when and whether BCBSMA, the parent, knew about the spreads in PADs and other drugs reimbursed through Medicare Part B. The timing of this knowledge is significant to the statute of limitations and other issues. The level of knowledge among BCBSMA employees was uneven. Remember, BCBSMA did not reimburse physicians based on AWP until 1995. Michael T. Mulrey began working in 1987 as a Senior Financial Analyst for Medical East and Medical West, and worked from 1994 to 1998 in the Provider Contracting area as a Senior Contract Analyst. (Mulrey Aff. ¶ 3.) He believed until 2004 that AWP was the price at which, on average, physicians were paying to purchase PADs. (*Id.* ¶ 14.) Deborah Devaux, who was Senior Vice President for Health Care Contract Management at BCBSMA, had a long history in the area of health care reimbursement. She said:

> I have personally been involved in negotiating such contracts, and in more recent years in supervising staff who negotiate such contracts. It is my ex-

28. If the staff model HMO clinics included Medicare patients, Medical West, Inc. generated revenue from this spread. (*See* 11/8/06 Tr. 103:10–103:22 (Coneys) (expressing uncertainty about whether Medicare patients were treated by the staff model HMO).)